



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 29 2001

Mr. Richard Woortman  
Manager Technical Services  
Cavex Holland B.V.  
Harmenjansweg 19  
P.O. Box 852  
Haarlem (Holland)  
NETHERLANDS

Re: K013336  
Trade/Device Name: Xantaglin Crono  
Regulation Number: 872.3660  
Regulation Name: Alginate Impression Material  
Regulatory Class: II  
Product Code: ELW  
Dated: October 8, 2001  
Received: October 9, 2001

Dear Mr. Woortman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

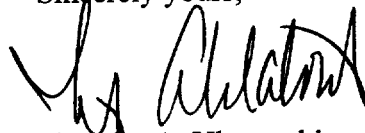
Please be advised that FDA's issuance of a substantial equivalence determination does not

mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski

Director

Division of Dental, Infection Control  
and General Hospital Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K013336

K013336

DEVICE NAME: Xantalgin Crono  
Alginate Impression Materials

## INDICATIONS FOR USE:

Xantalgin Crono is a dental impression material based on alginate. It is used for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. It is a general purpose impression material for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions etc.

Xantalgin Crono has the special characteristic of being a color-changing alginate: it becomes blue upon contact with water in the mixing bowl. It changes to violet indicating the end of the mixing time and loading the tray. Then it changes to pink indicating the moment to insert the tray into the mouth of the patient and finally it changes to white indicating the end of the setting time in the mouth.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED. )

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Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐  
(Optional Format 1-2-96)

Susan Pinner  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013336